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EXAMINER	
KASSA, TIGABU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,211	BAKKER ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed April 03, 2009. Claims 1-15 and 17-20 are currently pending. Claims 1-12 and 18-20 are under consideration in the instant office action. Claims 13-15 and 17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claim 16 is cancelled. Applicant's amendment has necessitated a new ground of rejection such as under 35 U.S.C. 103(a). Accordingly, this Action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed on 04/03/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-3, 5-8, 10, 18 and 20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398, IDS reference) in view of Subramaniam et al. (US Patent No. 6,113,795).

Applicant Claims

Applicant claims an antisolvent solidification process for preparing a solid composition comprising at least one organic or inorganic compound, wherein a liquid medium comprising at least one dissolved organic or inorganic compound is forced through a membrane which is positioned in a membrane module into one or more antisolvents or wherein one or more antisolvents are forced through a membrane which is positioned in a membrane module into a liquid medium comprising at least one organic or inorganic compound, and whereby the process is carried out as a continuous process and the membrane has up to 3 μm pore size and the shape of the membrane is selected from tubes, fibers, and spiral wounds, yielding a composition comprising solid particles comprising said organic and/or inorganic compound(s). In other embodiments, instant

claim 2 recites a process wherein the solidification is a crystallisation, the prepared solid particles are crystalline particles, the organic or inorganic compound is a crystallisable compound, and, optionally, said crystalline particles are recovered from the process. Instant claim 3 recites a process as recited in claim 1 wherein the liquid medium is separated from the one or more antisolvents by means of nanofiltration and wherein, optionally, the liquid medium and/or the antisolvent(s) is/are recycled. Instant claim 5 recites a process as recited in instant claim 1 wherein a nonsolvent is present in the liquid medium and/or in the one or more antisolvent. Instant claim 6 recites a process as recited in instant claim 1, wherein the organic or inorganic compound is a saccharide as per applicant's species election. Instant claim 7 recites a process as recited in claim 1 wherein the solid particles essentially consist of particles of only one inorganic or organic compound. Instant claim 8 recites a process as recited in instant claim 1 wherein the inorganic or organic compound is a pharmaceutical compound. Instant claim 10 recites a process as recited in claim 1 wherein the solid composition comprises a mixture of two or more pharmaceutical compounds. Instant claim 18 recites a process according to claim 1 wherein in an additional step a pharmaceutical dosage form is prepared from the composition. Instant claim 19 recites a process according to claim 18 wherein the dosage form is a tablet. Instant claim 20 recites a process according to claim 18 wherein the dosage form is a product for inhalation.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Jakupovic et al. teach a process for producing a pharmaceutical powder for inhalation comprising crystalline particles of an inhalation compound, comprising

dissolving an inhalation compound to be provided in crystalline particle form in a solvent; and introducing the solution containing the inhalation compound, in droplet form or as a jet stream into an anti-solvent which is miscible with the solvent and which is under agitation, under non-supercritical conditions (column 2, lines 26-34). Jakupovic et al. teach that once the compound is dissolved the solution is preferably added to the antisolvent through **a porous filter** having pores of 10-160 microns (column 4, lines 24-27). This teaching reads on the limitation reciting forcing the liquid medium through a membrane.

Jakupovic et al. teach an illustrative example where a solution of budesonide in methanol was added to water/ice at a rate of 1 ml/min, through a glass filter with a porosity of 40-90 microns, and with stirring with ultraturrax equipment. The obtained slurry contained **budesonide** crystalline particles of MMD 2.79 microns. 90% of the particles had a diameter of below 6.0 μm (column 5, lines 20-26, example 2).

Jakupovic et al. teach a list of medically useful compounds which may be provided in respirable particle form such as β2-adrenoteceptor agonists, glucocorticosteroids like budesonide etc (column 3, lines 8-32). Jakupovic et al. disclose the process may be used to prepare **carbohydrates (saccharides)** such as lactose, dextrose, melezitose, maltose, mannitol, trehalose and raffinose, as well as salts of fatty acids, bile salts, phospholipids and alkyl glycosides, which may be useful as penetration enhancers (column 3, lines 45-50). Furthermore, Jakupovic et al. teach the pharmaceutically acceptable additive may be prepared in the same manner as the medically useful compound, and the powders may then be mixed together, or a powder containing the medically useful compound and additive may be prepared in certain cases,

i.e. when the compound and additive have similar solubilities, by dissolving all of the desired substances together in the solvent (column 3, lines 50-57).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jakupovic et al. do not teach the membrane having up to 3 mm pore size and the shape of the membrane being tubes, fibres, and spiral wounds. These deficiencies are cured by the teachings of Subramaniam et al.

Subramaniam et al. teach processes and apparatuses that are provided for continuously harvesting particles from organic solution-laden near-critical and supercritical fluids. Broadly, the processes and apparatuses utilize a filter or separator comprising a thin membrane supported on a sintered stainless steel tube (see abstract). A feed stream comprising the desired particles, a supercritical antisolvent for the particles (preferably CO_2), and a solvent for the particles, is contacted with the membrane layer of the filter under supercritical conditions for the mixture of antisolvent and solvent (see abstract). The desired particles are retained by the filter while the solvent and most of the antisolvent pass through the filter, resulting in separation of the particles from the solvent (see abstract).

Subramaniam et al. teach the separator comprises first and second porous layers (column 3, lines 31-32). Subramaniam et al. teach the first layer is formed as a membrane, the membrane preferably includes pores having an average pore size of from about 0.08-0.12 μm, and preferably about 0.1 μm (column 3, lines 46-49). Subramaniam et al. teach that those skilled in the art will appreciate that the average pore size can be

adjusted to suit the particular application (column 3, lines 49-51). For example, the membranes can be selected for retaining particles having the following desired particle sizes: particles having an average size of less than about 0.5 μm for use in forming cancer treating agents or for use in intravenous injections; particles having an average size of from about 1-5 μm for use in inhalation therapy; and particles having an average size of from about 10-50 μm for applications where larger particles sizes are necessary (column 3, lines 51-59).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the process of Jakupovic et al. by using a membrane having up to 3 mm pore size and the shape of the membrane is selected from tubes, fibres, and spiral wounds, because Subramaniam et al. teach the use of such membranes for filtration for a similar process as described above for the preparation of solid crystal particles. The skilled artisan would have been motivated to use a membrane having up to 3 mm pore size and the shape of the membrane is selected from tubes, fibres, and spiral wounds in such a process, because Subramaniam et al. teach that those skilled in the art will appreciate that the average pore size can be adjusted to suit the particular application (column 3, lines 49-51). For example, the membranes can be selected for retaining particles having the following desired particle sizes: particles having an average size of less than about 0.5 mm for use in forming cancer treating agents or for use in intravenous injections; particles having an average size of from about 1-5 mm for use in inhalation therapy; and particles having an average size of from about

10-50 mm for applications where larger particles sizes are necessary (column 3, lines 51-59). With regard to the limitation reciting the process being continuous, Subramaniam et al. teach as described above a continuous process, furthermore, the skilled artisan would also consider the process described by Jakupovic et al. as being necessarily a continuous process. A skilled artisan would have had a reasonable expectation of success in combining the references, because both references address similar process of solidification of pharmaceutical compounds through the formation of solid crystal particles. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Nocent et al., *J. Pharm. Sci*, 90, 1620-1627.

Applicant Claims

The claimed subject matters of instant claim 1 are set forth above. Instant claim 4 recites a process according to claim 1 wherein an emulsion is formed before said composition comprising solid particles is obtained.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jakupovic et al. and Subramaniam et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jakupovic et al. and Subramaniam et al. do not explicitly teach a process of forming an emulsion before solid particles are formed. This deficiency is cured by the teachings of Nocent et al.

Nocent et al. disclose quasi-emulsion solvent diffusion method where "the drug is dissolved in solvent and the antisolvent phase (antisolvent and emulsifier) are prepared separately and maintained at different temperatures. Nocent et al. also disclose that the crystallization process incorporating the emulsifier is attractive because it can lead to significant improvements in the physical properties of materials, such as flowability, compressibility and compactibility (see page 1620). The solvent solution is then added to the antisolvent solution under agitation. Since interactions between drug and solvent being stronger than the interactions between solvent and antisolvent, the solvent is dispersed in the antisolvent and creates a quasi-emulsion. The formation of this unstable emulsion is induced by the increase in the interfacial tension between solvent and antisolvent. However, since emulsifier is added the emulsion is formed resulting in the

solvent and antisolvent diffusing in opposite directions, specially the antisolvent diffusing into the droplets, reducing the solubility of the drug and inducing crystallization inside the droplets" (see page 1621).

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Jakupovic et al. and Subramaniam et al. via the formation of an emulsion, because Nocent teaches a similar process of crystallization where a drug is dissolved in solvent and added to the antisolvent in the presence of an emulsifier to form an emulsion resulting in crystal particles of the drug. An ordinary skilled artisan would have been motivated to form an emulsion, because Nocent et al. teach that the crystallization process incorporating the emulsifier is attractive because it can lead to significant improvements in the physical properties of materials, such as flowability, compressibility and compactibility (see page 1620). Thus, an ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because all references teach similar processes of crystallization of chemical compounds using the solvent/antisolvent system, specifically, Nocent's process utilizing the addition of an emulsifier demonstrated to be useful during the crystallization process to form a stable emulsion form from the unstable quasi-emulsion formed as a result of interactions between drug and solvent being stronger than the interactions between solvent and antisolvent (see page 1621).

Claims 1, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Chen et al. (US Patent No 7,374,779) as evidenced by Nakagawa et al. (Japan J. Pharmacol. 29, 509-514, 1979).

Applicant Claims

The claimed subject matters of instant claims 1 and 8 are set forth above. Instant claim 9 recites a process according to claim 8, wherein the inorganic or organic pharmaceutical compound is 3-ketodesogestrel as per applicant's species election. Examiner also acknowledges that the species election for the pharmaceutical compound type is expanded to progesterone too.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jakupovic et al. and Subramaniam et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jakupovic et al. and Subramaniam et al. do not explicitly teach of a process of forming **progesterone** or **3-ketodesogestrel** crystal particles. This deficiency is cured by the teachings of Chen et al.

Chen et al. teach a novel pharmaceutical formulation that provides for increased absorption and bioavailability of active agents, particularly active agents that are administered orally (column 8, lines 58-61). Chen et al. disclose a list of active agents

that includes preferred sex hormones such as progestins, such as, **3-ketodesogestrel** (column 10, line 24).

Chen et al. teach that the active agent can be dissolved in appropriate solvent and subjected to crystallization (column 54, lines 35-37 and claim 8) via precipitation by antisolvent (column 54, lines 50-54).

Chen et al. disclose an illustrative example of a pharmaceutical formulation comprising **progesterone** (column 73, example 48).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical formulation of 3-ketodesogestrel or progesterone via the utilization of crystallization using precipitation by antisolvent, because as discussed above Chen teaches that the active agent can be dissolved in appropriate solvent and subjected to crystallization via precipitation by antisolvent to form pharmaceutical solid particles of **3-ketodesogestrel** or progesterone. Moreover, one of ordinary skill in the art would also recognize that substituting one anti-inflammatory agent such as progesterone as evidenced by Nakagawa et al. for another (e.g. budesonide) is obvious because the selection of a known material based on its suitability for its intended use supports a determination of *prima facie* obviousness (MPEP § 2144.07). A skilled artisan would have had a reasonable expectation of success because the anti-inflammatory agents will serve the same intended function healing inflammation after being crystallized through the same process.

Claims 1, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Maruyama et al. (US Patent No 5,512,092).

Applicant Claims

The claimed subject matters of instant claim 1 are set forth above. Instant claim 11 recites a process according to claim 1, wherein the solid particles are coated with a coating solution. Instant claim 12 recites a process according to claim 11, wherein the prepared solid composition comprises particles having a core coated with a coating material which comprise a pharmaceutical compound.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jakupovic et al. and Subramaniam et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jakupovic et al. and Subramaniam et al. do not teach of a process of coating the solid particles, which are formed via the above discussed process, by passing a liquid medium comprising dissolved coating material through a membrane into a suspension of particles. This deficiency is cured by the teachings of Maruyama et al.

Maruyama et al. disclose a method for preparing an aqueous emulsion for coating solid pharmaceutical preparations comprising the steps of dissolving a cellulosic polymer in a mixed solvent of water and an organic solvent capable of being admixed with water

in any rate to give a polymer solution, self-emulsifying the polymer solution by mixing with water and then concentrating the resulting emulsified stock solution. The concentration is carried out by removing a part of the liquid components while passing it through a membrane for ultrafiltration until the polymer concentration of the resulting emulsion reaches a level of not less than 7% by weight (see Abstract).

Maruyama et al. disclose the coating treatment is performed by spraying to the solid particles (column 4, line 21).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Jakupovic et al. and Subramaniam et al. by coating the solid particles, because, Maruyama as discussed above teaches coating pharmaceutical solids utilizing drug coating materials. One of ordinary skilled in the art would be motivated to do the coating because it will serve not only protect a drug having low resistance to acids from the attack thereof in the stomach, but also protect the gastric mucous membrane from the attack of the drug which may stimulate and damage the wall of the stomach and is dissolved after the arrival at the intestines wherein the pharmaceutical preparation shows its desired pharmacological action as described by Maruyama et al. With regard to passing the coating solution through a membrane one of ordinary skilled in the art would be motivated to do that, because the step would help to concentrate and adjust the concentration of the coating solution to a needed level as also demonstrated by Maruyama et al.. A skilled artisan

would have had a reasonable expectation of success in combing the references, because all references are concerned with pharmaceutical solid particles.

Claims 1, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Saim et al. (US Patent No 6,858,166).

Applicant Claims

The claimed subject matters of instant claims 1 and 18 are set forth above. Instant claim 19 recites a process according to claim 18, wherein the dosage form is a tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jakupovic et al. and Subramaniam et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jakupovic et al. and Subramaniam et al. do not teach the dosage in the form of a tablet. This deficiency is cured by the teachings of Saim et al.

Saim et al. teach a method for solute particle precipitation, retention and dispersion in a carrier material by taking advantage of the unique properties of pressurized gaseous (e.g. supercritical) fluids to precipitate solute particles from solution and by effectively retaining and dispersing the precipitated particles in a carrier material having good flow and handling properties (column 5, lines 51-58).

Saim et al. teach that the blends, granulations and partially or fully coated carrier materials, or mixtures thereof, produced by the methods are particularly suited for pharmaceutical processing into various pharmaceutical formulations and dosage forms, such as tablets and capsules (column 6, lines 42-46).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Jakupovic et al. and Subramaniam et al. by preparing the dosage in the form of tablets, because Saim et al. teach that such particles can be prepared in the form of tablets. One of ordinary skilled in the art would be motivated to prepare the dosage in the form of tablets, because tablets are conventionally known pharmaceutical dosage form. A skilled artisan would have had a reasonable expectation of success in combing the references, because both references are concerned with pharmaceutical solid particles.

Conclusion

Claims 1-12 and 18-20 are rejected. Claims 13-15 and 17 are withdrawn. Claims 16 is cancelled. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 6/15/09

/Mina Haghighatian/
Primary Examiner, Art Unit 1616